# Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 15, 1998 list were made in September, 1998

## New Approvals

### ANADA Number: 200-055

| | |
|---|---|
| Pioneer Product: | 045-290 |
| Trade Name: | VetaKet™ |
| Ingredients: | Ketamine hydrochloride |
| Sponsor: | Lloyd, Inc. |
| Approval Date: | 08/03/98 |
| Status: | Prescription only |
| Route: | Intramuscular |
| Species: | Feline, subhuman primates |
| Drug Form: | Liquid (solution) |
| Concentration: | 100 mg/mL |
| Indications: | For restraint or as the sole anesthetic agent for diagnostic or minor, brief, surgical procedures that do not require skeletal muscle relaxation. It may be used in subhuman primates for restraint. |

*21CFR 522.1222*

### ANADA Number: 200-197

| | |
|---|---|
| Pioneer Product: | 065-252 |
| Trade Name: | Streptomycin Oral Solution |
| Ingredients: | Streptomycin sulfate |
| Sponsor: | Contemporary Products, Inc. |
| Approval Date: | 08/03/98 |
| Status: | Over-the-counter |
| Route: | Oral |
| Species: | Avian (chickens), porcine, bovine (calves) |
| Drug Form: | Liquid (solution) |
| Concentration: | 250 mg/mL |
| Indications: | Chickens: For the treatment of non-specific infectious enteritis caused by organisms susceptible to streptomycin sulfate.<br>Swine and calves: For the treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella* spp. susceptible to streptomycin sulfate. |
| Tolerance: | 21 CFR 556.610: Tolerances in uncooked edible tissues of chickens, swine, and calves are 2 ppm in kidney and 0.5 ppm in other tissues. |
| Withdrawal: | Cattle 2 days; chickens 4 days. |

*21CFR 520.2158 and 510.600*

## NADA Number: 141-068

| | |
|---|---|
| Trade Name: | Baytril 100 Injectable Solution |
| Ingredients: | Enrofloxacin |
| Sponsor: | Bayer Corp. |
| Approval Date: | 07/24/98 |
| Status: | Prescription only |
| Route: | Subcutaneous |
| Species: | Bovine |
| Drug Form: | Liquid (solution) |
| Concentration: | 100 mg/mL |
| Indications: | For the treatment of bovine respiratory disease (BRD) associated with *Pasteurella haemolytica, Pasteurella multocida,* and *Haemophilus somnus*. |
| Tolerance: | 21CFR 556.228: 0.1 ppm for the marker residue (desethylene ciprofloxacin) has been established in liver of cattle. |
| Withdrawal: | 28 days |
| Patent No.: | 4,670,444 Expiration date: 06/02/2004<br>5,077,429 12/31/2008 |
| Exclusivity: | 3 years |

*21CFR 522.812* and *556.228*

## NADA Number: 141-108

| | |
|---|---|
| Trade Name: | EtoGesic™ |
| Ingredients: | Etodalac |
| Sponsor: | Fort Dodge Animal Health |
| Approval Date: | 07/22/98 |
| Status: | Prescription only |
| Route: | Oral |
| Species: | Canine |
| Drug Form: | Tablet |
| Concentration: | 150 and 300 mg/tablet |
| Indications: | For the management of pain and inflammation associated with osteoarthritis in dogs. |
| Patent No.: | 4,076,831 Expiration date: 02/28/1997 |
| Exclusivity: | 5 years |

*21CFR 520.870*

## NADA Number: 141-102

| | |
|---|---|
| Trade Name: | Deccox®, BMD® |
| Ingredients: | Decoquinate, bacitracin methylene disalicylate (BMD) |
| Sponsor: | Alpharma, Inc. |
| Approval Date: | 08/03/98 |
| Status: | Over-the-counter |
| Route: | Oral |
| Species: | Avian (broiler chickens) |
| Drug Form: | Type A medicated articles to make Type C medicated feeds |
| Concentration: | Decoquinate 6% activity per pound of Type A medicated article; bacitracin methylene disalicylate 10, 25, 30, 40, 50, 60 or 75 grams activity per pound of Type A medicated article. |
| Indications: | For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti*, and for increased rate of weight gain and improved feed efficiency. |
| Tolerance: | 21 CFR 556.170 Decoquinate: 2 ppm in uncooked edible tissues of chickens other than skeletal muscle and 1 ppm in skeletal muscle.<br>21 CFR 556.70 Bacitracin: 0.5 ppm negligible residue in uncooked edible tissues of chickens. |
| Withdrawal: | Zero days |

*21CFR 558.76* and *558.195*

## Supplemental Approvals

### NADA Number: 140-852

| | |
|---|---|
| Trade Name: | Monteban®, BMD®, 3-Nitro® |
| Ingredients: | Narasin, bacitracin methylene disalicylate, roxarsone |
| Sponsor: | Alpharma, Inc. |
| Approval Date: | 07/29/98 |
| Status: | Over-the-counter |
| Route: | Oral |
| Species: | Avian (broiler chickens) |
| Drug Form: | Type A medicated articles to make Type C medicated feeds |
| Concentration: | Narasin: 45 g/lb<br>Bacitracin methylene disalicylate: 10, 25, 30, 40, 50, 60, or 75 g/lb<br>Roxarsone: 45.4, 90, or 227 g/lb |
| Indications: | For prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* as an aid in the prevention and control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, for increased rate of weight gain, improved feed efficiency, and improved pigmentation in broiler chickens. |
| Tolerance: | 21 CFR 556.428 Narasin: A tolerance for narasin residues in chickens is not needed. The safe concentrations for total narasin residues in uncooked edible chicken tissues are: 0.6 ppm muscle; 1.8 ppm in liver; 1.2 ppm in skin with adhering fat.<br>21 CFR 556.70 Bacitracin: 0.5 ppm negligible residue in uncooked edible tissues of chickens<br>21 CFR 556.60 Arsenic residues (from roxarsone): 0.5 ppm in uncooked edible muscle and 2 ppm in uncooked edible by-products of chickens. |
| Withdrawal: | 5 days |

This supplemental application provides for two new claims for the combined use of three approved Type A medicated articles (narasin, bacitracin methylene disalicylate, and roxarsone) in the manufacture of Type C medicated feeds, rather than a premix incorporating all three of these compounds.

*21CFR 558.363*

# Actions Taken by FDA Center for Veterinary Medicine

## NADA Number: 113-232

| | |
|---|---|
| Trade Name: | Liquamycin® LA-200® |
| Ingredients: | Oxytetracycline |
| Sponsor: | Pfizer, Inc. |
| Approval Date: | 07/21/98 |
| Status: | Over-the-counter |
| Route: | Intramuscular, intravenous, subcutaneous |
| Species: | Bovine (lactating dairy cattle, beef cattle, nonlactating dairy cattle, calves including preruminating veal calves), porcine |
| Drug Form: | Liquid (suspension) |
| Concentration: | 200 mg/mL |
| Indications: | Bovine: for the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp.; bovine keratoconjunctivitis caused by *Moraxella bovis*; foot-rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused by *Leptospira pomona*; and wound infections and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline.<br>Porcine: for the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*; pneumonia caused by *Pasteurella multocida*; and leptospirosis caused by *Leptospira pomona*. In sows, as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*. |
| Tolerance: | 21 CFR 556.500: The ADI (acceptable daily intake) for total residues is 25 micrograms/kilogram of body weight per day. Tolerances are established for the sum of residues in tissues as follows: 2 ppm in muscle, 6 ppm in liver, 12 ppm in fat and kidney, 0.3 ppm in milk. |
| Withdrawal: | 28 days slaughter cattle and swine; 4 days milk |
| Exclusivity: | 3 years |

This supplemental application provides for the use of oxytetracycline in an additional species, lactating dairy cattle. This product had already been approved in beef cattle, nonlactating dairy cattle and swine.

*21CFR 522.1660 and 556.500*

# New Sponsor

Contemporary Products, Inc.
3788 Elm Springs Rd.
Springdale, AR 72764-6067
Drug labeler code: 055462

# Change of Sponsor

## NADA Number: 100-840

From: Fujisawa USA, Inc.
To: American Pharmaceuticals Partners, Inc.
2045 North Cornell Ave.
Melrose Park, IL 60160
Drug labeler code: 063323